

Message Text

PAGE 01 SALVAD 00109 042033Z
ACTION H-02

INFO OCT-01 ARA-14 ISO-00 OES-09 /026 W
-----101482 051813Z /44

R 041133Z AUG 78
FM AMCONSUL SALVADOR
TO SECSTATE WASHDC 0424
INFO AMEMBASSY BRASILIA
AMCONSUL RIO DE JANEIRO
AMCONSUL SAO PAULO

UNCLAS SALVADOR 0109

STATE PLEASE PASS TO DR. THOMAS COLIBER, HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE ON POPULATION.

E.O. 11652:N/A
TAGS: TBIO, SPOP
SUBJECT: TESTIMONY BAHIA POPULATION /BIRTH CONTROL EXPERT BEFORE
HOUSE OF REPRESENTATIVES.

FOLLOWING IS TEXT OF STATEMENT DR. ELSIMAR COUTINHO WILL DELIVER
ON AUGUST 9.

ZZZZZ

TESTIMONY BY DR. ELSIMAR COUTINHO

THE EARLY CLINICAL TRIALS WITH DEPO-PROVERA(M.P.A.) CARRIED OUT
IN THE LATE FIFTIES AND EARLY SIXTIES FOCUSED ON ITS POTENTIAL
AS AN UTERO-INHIBITORY DRUG TO BE USED IN THE TREATMENT OF PREMATURE
LABOUR. OUR OWN INVOLVEMENT WITH THE COMPOUND STARTED
AT THAT TIME WHEN WE TREATED WOMEN IN PREMATURE LABOUR WITH HIGH
DOSES OF M.P.A. AT THAT TIME, NO OTHER TREATMENT FOR THE PREVENTION
OF PREMATURE LABOUR WAS AVAILABLE. TWENTY WOMEN IN PREMATURE LABOUR HAVE
BEEN TREATED WITH DEPO-PROVERA, BUT AS THE DRUG FAILED TO STOP LABOUR

,
UNCLASSIFIED

PAGE 02 SALVAD 00109 042033Z

THE STUDY WAS DISCONTINUED. THE FOLLOW-UP OF THESE WOMEN REVEALED
THAT NO PREGNANCY OCCURRED FOR AS LONG AS ONE YEAR FOLLOWING THERAPY,
SUGGESTING A PROLONGED CONTRACEPTIVE EFFECT. THESE FINDINGS
WERE REPORTED TO THE UPJOHN COMPANY WHO HAVE SHOWN AN INTEREST IN
STUDYING THIS SIDE EFFECT OF THE PROGESTIN. THE SERENDIPITOUS
FINDING LED TO AN INVESTIGATION OF THE CONTRACEPTIVE EFFECTS
OF DEPO-PROVERA, FIRST IN SMALL SELECT GROUPS AND LATER IN LARGE
POPULATIONS. WE HAVE BEEN INVOLVED WITH THESE VERY EARLY TRIALS IN
WHICH THE EFFECTIVE DOSES WERE ESTABLISHED (1). THE EFFECTIVE DOSE
FOR ONE MONTH CONTRACEPTION WAS FOUND TO BE IN THE RANGE OF 50MG.

IN COMBINATION WITH A LONG ACTING ESTROGEN, AS LITTLE AS 25MG. OF DEPO-PROVERA WAS FOUND TO PROVIDE EFFECTIVE CONTRACEPTION FOR ONE MONTH (2). WITH HIGHER DOSES, WITHOUT ESTROGEN, 150MG OF DEPO-PROVERA AFFORDED PROTECTION FOR 3 MONTHS , AND AT 400MG, THE EFFECT WAS EXTENDED TO 6 MONTHS. FURTHER EXTENSION OF THE CONTRACEPTIVE ACTION WAS ACHIEVED WITH HIGHER DOSES.

IN MEN, DEPO-PROVERA MAY ALSO BE USED AS A CONTRACEPTIVE BUT HIGHER DOSES ARE REQUIRED FOR EFFECTIVE SUPPRESSION OF SPERMATOGENESIS.(3).

SEVERAL CLINICAL TRIALS HAVE BEEN CARRIED OUT IN ORDER TO DETERMINE THE ACCEPTABILITY, EFFICACY AND POSSIBLE SIDE EFFECTS OF DEPO-PROVERA IN LONG TERM TREATMENTS. WE HAVE CONDUCTED TWO SUCH STUDIES IN WHICH 200 WOMEN PARTICIPATED. IN ONE STUDY, 100 WOMEN SHOULD RECEIVE 150MG OF DEPO-PROVERA EVERY THREE MONTHS FOR 10 YEARS. IN THE SECOND STUDY, 100 WOMEN SHOULD RECEIVE THE HIGHER DOSE OF 400 MG EVERY SIX MONTHS ALSO FOR TEN YEARS. UNFORTUNATELY NOT ALL SUBJECTS REMAINED IN THE STUDY FOR THE ENTIRE DURATION OF THE PLANNED OBSERVATION. DISCONTINUATION WAS DUE MAINLY TO BLEEDING ABNORMALITIES AND AMENORRHEA. APPROXIMATELY 6,000 WOMEN MONTHS OF OBSERVATION WERE RECORDED.

UNCLASSIFIED

PAGE 03 SALVAD 00109 042033Z

IN THE ABOVE MENTIONED STUDY, SPECIAL ATTENTION WAS GIVEN TO CHANGES IN CERVICAL CYTOLOGY WHICH COULD REVEAL PRE-CANCEROUS LESIONS, AND TO THE DEVELOPMENT OF BREAST NODULES. PAPANICOLAU SMEARS AND A COMPLETE GYNECOLOGICAL EXAMINATION WAS CARRIED OUT REGULARLY IN ALL SUBJECTS AT INTERVALS OF THREE MONTHS. IN ONLY ONE SUBJECT MAMMARY NODULES DEVELOPED DURING TREATMENT BUT THESE WERE FOUND TO BE BENIGN. IN NONE OF THE WOMEN WERE PRE-MALIGNANT OR MALIGNANT ALTERATIONS DETECTABLE IN THE CERVIX.

BECAUSE OF THE RELATIVELY LOW INCIDENCE OF BOTH CERVICAL AND BREAST CANCER, THE SMALL NUMBER OF WOMEN INVOLVED IN THESE TRIALS DISALLOWS STATISTICALLY SIGNIFICANT CONCLUSIONS BASED ON THE NON-OCCURRENCE OF TUMOURS. HOWEVER, THE SAME INCONCLUSIVENESS APPLIES TO THE ONLY STUDY THAT TO MY KNOWLEDGE HAS EXAMINED THE ASSOCIATION BETWEEN DEPO-PROVERA AND BREAST NODULES IN WOMEN (4). IN FACT DEPO-PROVERA IS WIDELY PRESCRIBED AS AN ESTROGEN ANTAGONIST IN THE TREATMENT OF ESTROGEN DEPENDENT BREAST NODULES IN WOMEN . IT IS ALSO ONE OF THE VERY FEW STEROID COMPOUNDS USED IN THE TREATMENT OF ENDOMETRIAL CANCER. REGARDING CERVICAL DISPLASIA THE INADEQUACY OF THE SAMPLE IS EVEN GREATER BECAUSE OF CONFOUNDING FACTORS SUCH AS SEXUAL BEHAVIOUR AND SOCIO-ECONOMIC FACTORS.

TO MY KNOWLEDGE, TWO SURVEYS HAVE REPORTED A HIGHER RATE OF ABNORMAL CYTOLOGY IN WOMEN USING DEPO-PROVERA THAN IN NON -USERS (5,6). HOWEVER, THE DIAGNOSTIC CRITERIA USED IN THESE STUDIES MAY HAVE BEEN DIFFERENT FROM OURS AND FROM OTHER STUDIES WHICH FAILED TO FIND ANY DIFFERENCE IN THE INCIDENCE OF ABNORMAL CYTOLOGY

BETWEEN WOMEN USING DEPO-PROVERA AND NON-USERS.

IN CONCLUSION I WOULD SAY THAT THE HUMAN DATA PRESENTLY AVAILABLE IS INADEQUATE TO ASSESS THE INFLUENCE OF LONG TERM USE OF DEPO-PROVERA IN THE INCIDENCE OF CERVICAL AND BREAST CANCER IN WOMEN. IN VIEW OF THE PROGESTIN'S ANTAGONISM TO ESTROGEN, I WOULD DEEM AN UNFAVOURABLE EFFECT ON THE INCIDENCE OF BREAST CANCER UNLIKELY. ON THE OTHER HAND, IN VIEW OF CHANGES IN SEXUAL BEHAVIOUR WHICH UNCLASSIFIED

PAGE 04 SALVAD 00109 042033Z

MAY RESULT FROM THE USE OF CONTRACEPTION, A FAIR ASSESSMENT OF THE EFFECT OF DEPO-PROVERA ON THE INCIDENCE OF CERVICAL CANCER WOULD HAVE TO BE BASED ON A COMPARISON BETWEEN DEPO-PROVERA USERS, USERS OF ORAL CONTRACEPTIVES AND USERS OF OTHER EFFECTIVE METHODS OF CONTRACEPTION.

PROF. ELSIMAR M. COUTINHO

BIOGRAPHICAL NOTES

DR. ELSIMAR METZKER COUTINHO, BORN ON MAY 18, 1930, COMPLETED HIS SECONDARY EDUCATION AT THE STATE COLLEGE OF BAHIA. HE CONTINUED HIS EDUCATION AT THE UNIVERSITY OF BAHIA WHERE HE OBTAINED DEGREES IN PHARTACY AND BIOCHEMISTRY AND IN MEDICINE IN 1951 AND 1956 RESPECTIVELY. FOLLOWING GRADUATION FROM MEDICAL SCHOOL, HE ACCEPTED A FELLOWSHIP FROM THE FRENCH GOVERNMENT TO STUDY UNDER CLAUDE FROMAGEOT IN PEPTIDE HORMONE RESEARCH IN PARIS. IT WAS AT THIS TIME THAT HE BECAME INTERESTED IN THE STUDY OF THE MECHANISM OF HORMONE ACTION-A FIELD WHICH HAS CONTINUED TO OCCUPY MUCH OF HIS ATTENTION.

AFTER RETURNING FROM FRANCE, DR. COUTINHO BECAME AN ASSOCIATE PROFESSOR OF BIOCHEMISTRY AT THE UNIVERSITY OF BAHIA AND SUBSEQUENTLY RECEIVED A FELLOWSHIP FROM THE ROCKEFELLER FOUNDATION TO UNDERTAKE RESEARCH AT THE ROCKEFELLER INSTITUTE IN NEW YORK. HERE HE WORKED , AS A GUEST INVESTIGATOR, AT G. CORNER'S LABORATORY IN COLLABORATION WITH DR. A. CSAPO.

DR. COUTINHO HAS PARTICIPATED AS A GUEST SPEAKER IN SEVERAL INTERNATIONAL CONGRESSES AND HIS WORK HAS BEEN SUPPORTED BY A NUMBER OF FOUNDATIONS. CURRENTLY, HE IS A FULL PROFESSOR AT THE UNIVERSITY OF BAHIA AND IS ENGAGED IN A PROGRAM IN REPRODUCTIVE BIOLOGY UNDER THE AUSPICES OF THE FORD FOUNDATION. /HIS MORE UNCLASSIFIED

PAGE 05 SALVAD 00109 042033Z

IMPORTANT PUBLICATIONS DEAL WITH THE MECHANISM OF ACTION OF HORMONES AND THE ROLE OF IONS IN REGULATORY PHENOMENA. SOME OF HIS MORE RECENT WORK IS CONCERNED WITH THE DEVELOPMENT OF NEW CONTRACEPTIVE TECHNIQUES AND THE STUDY OF TUBAL AND

UTERINE PHYSIOLOGY.

DURING THE LAST TWO YEARS DR. COUTINHO BECAME ASSOCIATED WITH SEVERAL PROGRAMS AT THE WORLD HEALTH ORGANIZATION IN HUMAN REPRODUCTION AT THE WORLD HEALTH ORGANIZATION AS A MEMBER OF THE ADVISORY GROUP TO THE EXPANDED PROGRAM IN HUMAN REPRODUCTION AND DIRECTOR OF WHO CLINICAL RESEARCH CENTER.

AS A CONSULTANT AND ACTIVE MEMBER OF THE INTERNACIONAL COMMITTEE FOR CONTRACEPTIVE RESEARCH, DR. COUTINHO IS ALSO ENGAGED IN NUMEROUS RESEARCH PROJECTS AIMED AT THE DEVELOPMENT OF NEW CONTRACEPTIVE METHODS AT THE POPULATION COUNCIL.....
WHITNEY

UNCLASSIFIED

<< END OF DOCUMENT >>

Message Attributes

Automatic Decaptioning: X
Capture Date: 26 sep 1999
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: POPULATION, BIRTH CONTROL, TEXT, TEXTS
Control Number: n/a
Copy: SINGLE
Draft Date: 04 aug 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978SALVAD00109
Document Source: ADS
Document Unique ID: 00
Drafter: n/a
Enclosure: n/a
Executive Order: N/A
Errors: n/a
Expiration:
Film Number: D780321-1105
Format: TEL
From: SALVADOR
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t197808122/baaafbgj.tel
Line Count: 179
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, TEXT ON MICROFILM
Message ID: 49d6f759-c288-dd11-92da-001cc4696bcc
Office: ACTION H
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 4
Previous Channel Indicators:
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 29 mar 2005
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: N/A
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 1589174
Secure: OPEN
Status: NATIVE
Subject: TESTIMONY BAHIA POPULATION /BIRTH CONTROL EXPERT BEFORE HOUSE OF REPRESENTATIVES.
TAGS: TBIO, SPOP
To: STATE INFO BRASILIA MULTIPLE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/49d6f759-c288-dd11-92da-001cc4696bcc
Review Markings:
Sheryl P. Walter
Declassified/Released
US Department of State
EO Systematic Review
20 Mar 2014
Markings: Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014